IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA

UNITED STATES OF AMERICA EX REL. JUAN N. WALTERSPIEL, M.D., F.A.A.P.,	)	1:09-cv-1086 LJM-DML
Plaintiffs;	)	CASE NO. _____
v.	)	
BAYER A.G., QUINTILES TRANSNATIONAL CORP., JOHN DOE, JOE DOE, AND JANE DOE,	)	**TRIAL BY JURY REQUESTED**
Defendants.	)	

COMPLAINT
(To Be Filed In Camera and Under Seal Pursuant to 31 U.S.C. § 3730(b)(2))

Qui Tam Plaintiff United States of America ex rel. Juan N. Walterspiel, M.D. and relator Juan N. Walterspiel, M.D., F.A.A.P., pursuant to the False Claims Act, 31 U.S.C. § 3729 et seq., hereby submit their complaint and allege as follows:

I. JURISDICTION

1. Jurisdiction is provided by the False Claims Act, 31 U.S.C. §§ 3730, 3732(a). *Qui Tam* Plaintiff/Relator Dr. Walterspiel seeks in this action, pursuant to 31 U.S.C. § 3730, remedies including fines and penalties and damages on behalf of the United States Government, and the relator's share on his own behalf, for violations of 31 U.S.C. § 3729 including the submission of false claims and false statements by Defendants. Additional facts related to the specific jurisdictional requirements of the False Claims Act are stated

in the paragraphs which follow in this section and in the subsequent sections of this complaint, and each of these paragraphs are incorporated here by reference.

2. Jurisdiction of the Court to hear this action is also provided by 28 U.S.C. § 1331, as this action involves one or more federal questions.

3. This Complaint is to be filed in camera and maintained under seal for at least 60 days, pursuant to 31 U.S.C. § 3730(b)(2), and is not to be served on Defendants thereafter until the Court so orders.

4. Pursuant to 31 U.S.C. § 3730(b)(2), a copy of this Complaint and a written disclosure of substantially all material evidence and information possessed by *Qui Tam* Relator Dr. Walterspiel related to the claims brought in this complaint have been served on the United States Government, including the United States Attorney, pursuant to rule 4(d)(4) of the Federal Rules of Civil Procedure. A copy of this complaint has also been served upon the Attorney General of the United States.

5. Prior to filing this Complaint, *Qui Tam* Relator Dr. Walterspiel voluntarily provided to the United States Government the information in his possession regarding the False Claims Act violations addressed in this Complaint.

6. To the extent that claims herein involve matters which have been previously publicly disclosed, the claims herein were not based upon the public disclosures of such matters.

7. *Qui Tam* Relator Dr. Walterspiel is an original source of the information and evidence he brings forward in support of the False Claims Act claims stated herein, as "original source" is defined in 31 U.S.C. § 3730(e)(4). Dr. Walterspiel has direct and independent knowledge of the information on which the allegations in this Complaint is based.

II. VENUE

8. Venue is proper in this Court pursuant to 31 U.S.C. § 3732(a). Defendant Bayer A.G. conducts business in the Northern District of Indiana and maintains manufacturing and related facilities in the cities of Elkhart and Mishawaka, Indiana.

9. Section 3732(a) of the Act provides that "[a]ny action under 3730 may be brought in any judicial district in which the defendant or, in the case of multiple defendants, any one defendant can be found, resides, transacts business, or in which any act proscribed by section 3729 occurred."

III. PARTIES

A. PLAINTIFF/RELATOR

10. Relator Dr. Juan N. Walterspiel is a licensed experienced physician and academician who resides in Belmont, California.

11. Dr. Walterspiel holds medical licenses in California, Georgia, Texas, and the European Union.

12. Dr. Walterspiel is board certified in pediatrics and infectious diseases.

13. Dr. Walterspiel has interacted with regulatory authorities worldwide to negotiate development plans and participated in the development of sections of Investigational New Drug applications (IND) and New Drug Applications (NDAs) that have led to successful market approvals.

14. Dr. Walterspiel has implemented development plans and protocols for clinical trials, conducted international investigator and site selections and study oversight.

15. Dr. Walterspiel has led successful international teams in IND and NDA submissions, achieving market approvals in the U.S. and the EU for various drugs.

16. Relator Dr. Walterspiel worked as independent contractor for Bayer in 2002. His contractual obligations were to retrieve from electronic study databases, that were patient identifier free, information on selected adverse events (AE). This information was presented by Dr. Walterspiel as short and medically meaningful narratives to Bayer's Independent Pediatric Safety Committee (IPSC).

17. Dr. Walterspiel has direct, independent and personal knowledge of the facts constituting Defendant's violations of the False Claims Act alleged herein.

18. Dr. Walterspiel has direct, independent and personal knowledge of the facts demonstrating that Defendant's violations of the False Claims Act alleged herein are knowing violations.

19. Dr. Walterspiel has direct, independent and personal knowledge that the false claims presented by Defendant alleged herein were knowingly presented.

20. Dr. Walterspiel acquired knowledge of the defendant's acts and false claims alleged herein through his own efforts, and without an intervening agency.

B. DEFENDANTS

21. Defendant Bayer A.G. is a large German pharmaceutical company which was at all times relevant hereto a corporation doing business in the State of Indiana

22. Bayer A.G.'s principal place of business in the United States is Pittsburgh, Pennsylvania.

23. Defendant Quintiles Transnational Corp. is an international corporation which conducts

business in more than twenty states of the United States, with its corporate offices in the United States located in Durham, North Carolina. Quintiles Transnational Corp. provides clinical trials including medical study data collection and source verification services under contract with pharmaceutical companies such as Bayer A.G.

24. Defendant Quintiles Transnational Corp. collected Ciprofloxacin (Cipro®) pediatric data under contract with Bayer A.G. for the two studies at issue in this Complaint which Bayer used in support of Bayer's application for a six month market exclusivity extension for Cipro®.

25. Jane Doe worked for Quintiles Transnational Corp. during the years Quintiles Transnational Corp. was collecting data on Cipro® for Bayer A.G.

26. Jane Doe reviewed the false data submitted to Bayer by Quintiles Transnational Corp. and allowed the data to be submitted to Bayer, and thereafter to the United States in support of Bayer's Cipro® market exclusivity extension, while failing to disclose the falsity of the data. Jane Doe observed that the investigators had not followed the study protocol and its instructions (in a blatant manner by falsifying data) but knowingly did not report this finding to her superiors (or did so and her superiors and/or Bayer failed to inform the United States).

27. Joe Doe worked for Bayer A.G. during the years Quintiles Transnational Corp. was collecting data on Cipro® for Bayer A.G.

28. Joe Doe reviewed the false data submitted to Bayer by Quintiles Transnational Corp. and allowed the data to be submitted to the United States in support of Bayer's Cipro® market exclusivity extension while failing to disclose the falsity of the data. Joe Doe

observed that the investigators had not followed the study protocol (in a blatant manner by falsifying data) but knowingly did not report this finding to his superiors (or did so and his superiors failed to inform the United States).

29. John Doe worked for Quintiles Transnational Corp. during the years Quintiles Transnational Corp. was collecting data on Cipro® for Bayer A.G.

30. John Doe reviewed the Cipro® pediatric study data submitted to Bayer by its contractors, which data was subsequently submitted to the United States in support of Bayer's Cipro® market exclusivity extension, and observed from irregularities in the data that the investigators could not have obtained such data by following the study protocol, but knowingly did not report this finding to his superiors or Bayer notwithstanding his obligation to do so (or did so and his superiors and/or Bayer failed to inform the United States).

IV. CLAIMS FOR RELIEF

Facts Common to All Counts

31. The preceding paragraphs and fact allegations are incorporated herein by reference.

32. Ciprofloxacin is one of the most successful quinolone antimicrobials ever marketed.

33. Ciprofloxacin as well as all other compounds in the quinolone class destroy joint cartilage in juvenile animals.

34. Quinolone antimicrobials were considered to be contraindicated in children and not studied for market approval.

35. Legislative incentives to provide drugs for children -- i.e the Food and Drug

Administration's Modernization Act's (FDAMA) six months exclusivity extension -- changed this above referenced presumption and practice, and as a result Cipro® became the first commercially approved quinolone for a pediatric indication in December of 2003.

36. The FDA, based on bioterrorism concerns, gave emergency use permission for ciprofloxacin in children for prophylaxis and treatment of pediatric inhalation anthrax in August of 2000.

37. This conditional emergency approval was based on a risk / benefit analysis. It states: "However, because inhalational anthrax is lethal, the risk-benefit assessment indicates that use of Cipro® for this indication in pediatric patients is appropriate. Studies are currently under way to evaluate long-term safety, including effects on cartilage, in pediatric patients." This emergency approval was conditional on further acquisition of reliable cartilage safety data from studies such as the two studies performed by Bayer.

38. When ciprofloxacin became available in the late nineteen eighties, the medical need for an oral medication to treat Pseudomonas aeruginosa infection in pediatric patients with cystic fibrosis (CF) was compelling enough that the academic pediatric infectious diseases community (including the Relator's division), took it up to study ciprofloxacin in these children and adolescents. Several of these studies were sponsored by Bayer.

39. Ciprofloxacin's pharmacokinetics in children, including the differences in CF and limited safety were established in such non approval studies. Multiple reports on its subsequent off label use showed it to be safe enough to become one of the standard antimicrobial therapies in pediatric patients including those with cystic fibrosis, complicated urinary

tract infection, typhoid fever, salmonella infection, and pseudomonas osteochontritis. Bayer, prior to patent expiration, had no incentive for a market application for Cystic Fibrosis, because physicians were already prescribing it to saturation.

40. Ciprofloxacin exhibits genotoxicity in vitro, and administration to children with many years of life in front of them would have posed an unnecessary corporate risk for genetic adverse events and liabilities to emerge.

41. Pediatric research was limited to funding investigator initiated research and meetings to maintain good standing and increase the drugs visibility throughout its lifecycle.

42. Bayer A.G., a once leading German pharmaceutical company, has a history of controversy involving ethical issues.

43. Bayer A.G.'s fraudulent Cipro® exclusivity extension, which is the subject of this complaint, fits a pattern of prior business conduct that resulted in the avoidable deaths of citizens of the United States and other countries.

44. Bayer A.G. continued to advertise Aspirin® for pediatric use in South America after its association with Reye's syndrome was known.

45. Bayer's (Miles/Cutter division) human Factor VIII product for hemophilia was only taken off international shelves long after the company had undeniable knowledge that the product was contaminated with HIV, and after introducing a recombinant product in western countries in 1984.

46. Bayer's "me to" statin, cerivastatin – Baycol®, was inferior to the market leader, atorvastatin - Lipitor®. To gain market advantage, Bayer increased its dose. This resulted in muscle cell destruction prompting kidney failure at rates above those seen

with other statins. The company publicly denied having received sufficient reports on such incidents for the longest time possible until forced to withdraw the drug amid a widening scandal in August of 2001.

47. In May of 2008, Bayer A.G. was forced to finally withdraw its aprotinine Trasylol® product that was approved in 1993. Aprotinine was reported in the New England Journal of Medicine to have increased the risk for death over equally active comparators by 50%. The issue surfaced in 2006, in independent reviews by Mangano.

48. Bayer, by "clerical error," failed to provide the FDA and its ad hoc committee with safety data from 67,000 administrations. This "absence" of evidence misled the FDA to allow Bayer to continue to market aprotinine at $1,400 per patient over the $4 for the safer aminocaproic acid. More avoidable deaths occurred.

49. Bayer paid approximately $30 million to a generic company, Barr and Rugby Laboratories, now owned by Watson Pharmaceuticals, Inc. to prevent generic ciprofloxacin from reaching the market in a timely fashion.

50. After the 2001 anthrax attack, Bayer refused to consider lowering its price for national emergency needs and insisted on its patent protection, prompting the Canadian government to threaten to temporarily nullify the patent and gain access to their storage sites.

51. The Ciprofloxacin six months market exclusivity extension was granted to Bayer A.G. in December of 2003 for the pediatric indication complicated urinary tract infection, pyelonephritis.

52. Bayer had submitted to the FDA Bayer studies #100169 and #100201 in support of its

application for this Cipro® market exclusivity extension.

53. Relator Dr. Walterspiel worked as an independent contractor for Bayer in 2002. His contractual obligations were to retrieve from electronic study databases for Bayer studies #100169 and #100201, that were patient identifier free, information on selected adverse events (AE) including the musculoskeletal and central nervous system.

54. Relator Dr. Walterspiel worked as a consultant to Bayer's Health Care Division in West Haven, Connecticut from about mid-2002 into early 2003. Relator Dr. Walterspiel's qualifications for the position were his professional experience and board certification in pediatrics and pediatrics infectious diseases, and his previous experience with the use and research of Ciprofloxacin (a quinolone antibiotic) in children, as well as his previous involvement in the worldwide Trovafloxacin (Trovan® - also a quinolone antibiotic) pediatric clinical development program at Pfizer, Inc. in Groton, Connecticut. . His qualifications also allowed him to later work on Bristol Myers Squibb's pediatric Gatifloxacin (Tequin®, a quinolone antibiotic removed from the U.S. market in May 2006) licensing and postmarketing surveillance program.

55. Relator Dr. Walterspiel's responsibility was to prepare written narratives from the closed (no longer to be changed or added to) database for subjects entered into Bayer A.G. international pediatric Ciprofloxacin studies #100169 and #100201 in complicated urinary tract infections. Subject numbers were selected for preparation of a structured narrative whenever the data record indicated a musculoskeletal or neurological adverse event. The narratives were then presented by Dr. Walterspiel to an independent adjudication committee, Bayer's Independent Pediatric Safety Committee (IPSC),

alternating with teleconferences and meetings in person in New York, Atlanta and West Haven. The four member committee decided by majority vote on the possible causality to study drug, without knowing whether ciprofloxacin or a comparator antimicrobial was given. That is, Committee members came to treatment-blinded majority assessments on causality.

56. Dr. Walterspiel found improbable goniometry data (joint angle measurements) in some of the subjects under review and asked Mrs. Renee Perroncel, the senior clinical research associate that Bayer had assigned to Dr. Walterspiel, to help him find the correct data.

57. Ms. Perroncel agreed that the measurement data in question were wrong, was concerned about this and other aspects of the goniometry data, and brought the issue to the attention of Bayer's management. The Ciprofloxacin patent market exclusivity extension team was at that time led by a neurologist whose name is not immediately available to Relator Dr. Walterspiel.

58. Ms. Perroncel was asked by the neurologist to "confirm" the values by asking the investigators to sign that these values were measured at their sites, in the respective subjects and were correct. Ms. Perroncel told Relator Walterspiel shortly thereafter that signed letters from the investigators had arrived and were put into the file.

59. Relator Walterspiel's doubts about the integrity of the data and the goniometry being only the tip of the iceberg (or the eyes of the hippopotamus) were further increased when Dr. Walterspiel noticed a lack of variability from measurement to measurement from some sites compared to others and noticed a lack of an analysis to flag any suspect data in advance of the committee's periodic reviews. Such analytical tools, which are

commonly used by Pharmaceutical company statisticians prior to study databank closure, were taught to Dr. Walterspiel during a course at the FDA while he was working for Pfizer.

60. The false data and statements submitted by Defendants to the FDA which hid adverse effects of Ciprofloxacin in children were material to the FDA's decision to approve the six month patent market exclusivity extension for Bayer for Cipro®.

61. In an Anthrax attack, Homeland Security, the CDC, local health authorities and physicians may be handicapped, as a result of the false data submitted by Defendants, in making informed decisions regarding the administration of ciprofloxacin to children in various risk scenarios and parents and caretakers will also not be correctly informed regarding the short and long term safety of ciprofloxacin for children and adolescents compared to other agents or immunizations.

62. The fraudulent nature of the data is also material to decisions of the United States because the same investigators who engaged in this fraud and their knowing corporate sponsor have committed to the FDA to continue to collect follow-up safety data from a subset of the subjects studied, the results of which were to have been submitted to the FDA in 2008. A correct understanding of this fraudulent data could influence updated government statements on the short and long term safety of ciprofloxacin in children. Also, had the original fraud been disclosed, the same investigators and corporate sponsors would not have been approved for subsequent government studies or contracts.

63. Part of the safety data to be collected were the maximal and minimal angles expressed in (360) degrees, to which joints could be freely moved before, after and longer after study

drug or comparator administration. This was to be able to detect short and long term joint cartilage or tendon damage that would have led to a restriction in the range of free joint movement.

64. While scrolling through the pages of the electronic database, to retrieve any before and after joint angle changes in selected study subjects with adverse effects, Relator Dr. Walterspiel noted long rows of joint angle degree numbers that were obviously just "filled in." These numbers repeated themselves in endless fashion compared to those that were within norm for age range and, with expected small variations from measurement to measurement, that other investigators recorded. Some of these data also included implausible values. Relator also took to Mrs. Perroncel single random examples of anomalous data.

65. In addition, Relator Dr. Walterspiel noticed in reviewing this data that there were several data entries having values for joint angles that were scientifically impossible, i.e. joint angles indicating a range of movement for which the human limbs in question are not capable. One of such examples was carried by Relator to Mrs. Perroncel.

66. Dr. Walterspiel concluded from his review of the data that some of the data in the Bayer Cipro® pediatric studies had been falsified.

67. Professional and federal policy and protocols support the conclusion that once an investigator and/or assignee have been observed to have invented data that all data from the site are compromised and need to be discarded. The FDA has followed this standard at least since the revelations with the Sanofi- Aventis telithromycin - Ketek ® studies.

68. There is an obligation for such incidents of data falsification to be reported to regulatory

authorities, who may ban such investigators from participation in future approval submissions. Government contractors involved in such data falsification may be debarred, disqualified from future federal contracts for a period of years.

69. Relator passed on his findings regarding these data anomalies and apparent data falsification to the Bayer chief clinical research associate for the project, who passed it on in a watered down "job saving" way to her Bayer superior.

70. This Bayer superior directed the Bayer chief clinical research associate to elicit a letter from the respective investigator(s) to confirm that the data were obtained as claimed and accurate. Such confirmation(s) were promptly received. Relator's review of the data indicates that such confirmations were false, and should have appeared false on their face to the knowledgeable Bayer physician superior who requested them.

71. Bayer employed the clinical research organization (CRO) Quintiles Transnational Corporation for a faster recruitment of study subjects in additional North and South American countries.

72. The fraudulent data should have been clearly noticeable to Quintiles Transnational source verification personnel.

73. Both Quintiles Transnational and Bayer A.G. elected to take the option of knowingly submitting the Bayer Cipro® pediatric study data to the FDA without disclosure of the false and fraudulent data, so as to not jeopardize Bayer's $0.5 + billion in Cipro® sales and Quintiles Transnational's current and future contracts with Bayer and other drug companies.

74. Prior to the approval of the market exclusivity extension in December, 2003, Cipro®

worldwide sales were at over $1.1 Billion/year.

75. Consequently, it is estimated that during the 6 months market exclusivity extension Bayer would enjoy $550 million in worldwide sales.

76. An estimated 30% of this Bayer Cipro® income is from the U.S. market, or approximately $165 million.

77. The U.S. government's share - including Veterans Administration, Medicare, Medicaid, and DOD/strategic national stockpile push pack rotation - of U.S. sales is approximately 10%, or $16.5 million.

78. An additional portion of Bayer's total income from U.S. sales of CIPRO comes from sales to State governments.

79. History shows that the price for a generic drug levels at 10% of the branded price, but other countries with less strict patent laws were already selling CIPRO for one thirtieth of the price prior to 2003.

80. The loss to the U.S. government from Defendant's false claims relating to Cipro® during the 6 month market exclusivity extension is an estimated at minimum at $ 14.85 million.

81. Defendant Bayer A.G. has engaged in a continuing pattern of deception that has led to the avoidable deaths of US citizens, a pattern that combined with the fraud regarding the Cipro® market exclusivity extension would support a decision by the U.S. to impose the debarment sanction. This pattern of misconduct includes the deaths of children from AIDS through Factor VIII (1980s), the deaths of adults from kidney failure through Cerivastatin (2001), and most recently (2008) the deaths of adults from cardiac complications through Aprotinin.

82. The U.S. would have imposed debarment on Defendant Bayer had the fraud regarding the Cipro® pediatric market exclusivity extension been disclosed or discovered because of the special regulatory concern and sensitivity surrounding the regulation of drugs for vulnerable children. The experience with the homicidal Trovafloxacin studies in children in Nigeria (1996) motivates such appropriate precautionary policies regarding children.

83. Defendant Bayer also failed to honor the spirit of the 6 months exclusivity incentive by bypassing an approval application for cystic fibrosis and applying for a last minute approval in the more profitable area of extending the Cipro® drugs commercial lifecycle via pediatric use.

Count 1: Defendants Knowingly Presented Or Caused to Be Presented to, and Paid By, the United States False Claims for Payment Related to the Government's Purchase of the Drug Cipro® in Violation of 31 U.S.C. § 3729(a)(1)

84. The preceding paragraphs and fact allegations are incorporated herein by reference.

85. During December, 2003 and January through June of 2004, Defendant Bayer presented multiple requests for payment of funds from the United States under contracts with the United States for the purchase by the United States of Cipro® from Bayer A.G.

86. During December, 2003 and January through June of 2004, Defendants had actual knowledge of the fact that Bayer had obtained a Cipro® market exclusivity extension from the United States by fraud and/or the use of false statements and records, acted in deliberate ignorance of the truth or falsity of this fact, or acted in reckless disregard of the truth of this fact.

87. During December, 2003 and January through June of 2004, Defendants knew that the prices Bayer was charging the United States for Cipro® were falsely inflated as a result

of the Defendants having obtained via fraud and/or false statements a six months CIPRO market exclusivity extension.

88. Had Bayer A.G. not obtained a market exclusivity extension from the United States for Cipro® by fraud and/or the use of false statements and records, the United States would have been able to contract with Bayer A.G. or a competitor producing generic Cipro® for the purchase of Cipro® at a substantially reduced price, and the United States would not have approved or paid the claims for payment presented by Bayer A.G. to the United States at the falsely inflated price.

89. The United States paid more than ten million dollars to Bayer A.G. than it would otherwise have paid for Ciprofloxacin as a result of Defendants' fraud, false statements, conspiracy and false claims which resulted in the falsely inflated prices charged by Bayer A.G. to the United States.

90. As a result of Bayer A.G.'s fraud in obtaining the market exclusivity extension for Cipro®, every contract that Bayer A.G. obtained from the United States and entered into with the United States for the purchase of Cipro® during the market exclusivity extension period was a contract obtained under false pretenses and a contract fraudulently obtained, resulting in every claim for payment under each of these federal contracts being a false claim under the False Claims Act. *See, Harrison v. Westinghouse Savannah River Co.,* 176 F.3d 776 (4th Cir.1999).

91. The damages to the United States under the FCA from the false claims presented by Defendants would be at least $10,000,000.00 (prior to trebling as required under the False Claims Act).

Count 2:Defendants Knowingly Made and Used, Or Caused to Be Made and Used, False Statements and Records to Cause False Claims for Payment Related to the Purchase of the Drug Cipro® to be Presented to, and Paid By, the United States in Violation of 31 U.S.C. § 3729(a)(2)

92. The preceding paragraphs and fact allegations are incorporated herein by reference.

93. During December, 2003 and January through June of 2004, Defendant Bayer presented multiple requests for payment of funds from the United States under contracts with the United States for the purchase of Cipro® by the United States from Bayer A.G.

94. Prior to and during December, 2003, Defendants made, used, and caused to be made and used, false records and statements, including those related to false Cipro® study data described above, to obtain for Bayer a market exclusivity extension for Cipro. These false records and statements included false medical and scientific data records and reports, false data analyses, and false certifications of data as described above.

95. Defendants acted initially, during the Cipro® market exclusivity extension application and approval process, and on an on-going basis thereafter, with actual knowledge of the fact that these statements and records were false, acted in deliberate ignorance of the truth or falsity of these statements and records, or acted in reckless disregard of the truth of these statements and records.

96. During December, 2003 and January through June of 2004, Defendants knew that the prices Bayer was charging the United States for Cipro® were falsely inflated as a result of the Defendants having fraudulently obtained a six month market exclusivity extension for CIPRO by the use of these false records and statements.

97. Had Bayer A.G. not fraudulently obtained a market exclusivity extension from the United

States for Cipro® by the use of the Defendants' false statements and records, and had Bayer A.G. not continued to rely on those false statements and records, and had the Defendants disclosed the falsity of these statements and records to the United States after the Cipro® market exclusivity extension was obtained, the United States would have been able to contract with Bayer A.G. or a competitor producing generic Cipro® for the purchase of Cipro® at a substantially reduced price, and the United States would not have approved or paid the claims for payment presented by Bayer A.G. to the United States at the falsely inflated price.

98. Defendants initially, during the Cipro® market exclusivity extension application and approval process, and on an on-going basis thereafter, made false representations to the United States, by express and implied statements and certifications, that Defendant Bayer was legitimately entitled to the Cipro® market exclusivity extension and legitimately entitled to continue to enjoy a monopoly on the production and sale of Cipro® when Defendants knew that this market exclusivity extension had been obtained by the use of the aforementioned false statements and records.

99. The United States paid more than ten million dollars to Bayer A.G. than it would otherwise have paid for Cipro® as a result of Defendants' use of these false statements and records which resulted in Defendant Bayer's claims for payment to the United States being paid at falsely inflated prices.

100. As a result of Defendants' use of these false statements and records to fraudulently obtain the market exclusivity extension for Cipro® for Bayer, every contract that Bayer A.G. obtained from the United States and entered into with the United States for the purchase

of Cipro® during the market exclusivity extension period was a contract obtained under false pretenses and a contract fraudulently obtained.

101. As a result, every claim for payment under each of these federal contracts was a false claim under the False Claims Act, *See*, *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776 (4th Cir.1999), and Defendants' aforementioned use of false statements and records caused each of these false claims to be presented, approved, and paid.

102. The damages to the United States under the FCA from the Defendants' making and use of false records and statements to cause these false claims to be presented, approved, and paid would be at least $10,000,000.00 (prior to trebling as required under the False Claims Act).

Count 3:Defendants Conspired to Cause False Claims for Payment Related to the Purchase of the Drug Cipro® to be Presented to and Paid by the United States in Violation of 31 U.S.C. § 3729(a)(3)

103. The preceding paragraphs and fact allegations are incorporated herein by reference.

104. Defendants conspired to perform the acts described in the preceding paragraphs for the purpose and with the intent to defraud the United States, in violation of 31 U.S.C. § 3729(a)(3), by getting false or fraudulent claims approved or paid.

105. Prior to and during December, 2003 and January through June of 2004, Defendants conspired to submit multiple requests for payment of funds from the United States under contracts with the United States for the purchase of Cipro®.

106. Prior to the submission by Defendant Bayer A.G. of its application for a market exclusivity extension for Cipro®, and during the application and approval process, Defendants knew that the Cipro® market exclusivity extension application was based on

and made use of false statements, and false medical and scientific data, records, reports and analyses. Defendants conspired to make use of these false statements, data. Records, reports and analyses to fraudulently and falsely obtain from the United States a market exclusivity extension for the drug Cipro® so that Defendant Bayer could continue to enjoy a monopoly on the production and sale of Cipro®, and could continue to sell Cipro® to the United States at falsely inflated prices.

107. Had Defendants not conspired to fraudulently obtain a market exclusivity extension from the United States for Cipro® for Bayer by the use of false statements and records, the United States would have been able to contract with Bayer A.G. or a competitor producing generic Ciprofloxacin for the purchase of Ciprofloxacin at a substantially reduced price.

108. The United States paid more than ten million dollars to Bayer A.G. that it would not otherwise have paid for Ciprofloxacin as a result of Defendants' conspiracy which resulted in the falsely inflated prices charged by Bayer A.G. to the United States for Cipro®.

109. As a result of Defendants' conspiracy to fraudulently and falsely obtain the market exclusivity extension for Cipro® for Bayer, every contract that Bayer A.G. obtained from the United States and entered into with the United States for the purchase of Cipro® during the market exclusivity extension period was a contract obtained under false pretenses and a contract fraudulently obtained, resulting in every claim for payment under each of these federal contracts being a false claim under the False Claims Act. *See, Harrison v. Westinghouse Savannah River Co.,* 176 F.3d 776 (4th Cir.1999).

110. The damages to the United States under the FCA from the false claims presented by Defendant Bayer A.G. would be at least $10,000,000.00 (prior to trebling as required under the False Claims Act).

Count 4:Defendants Knowingly Presented Or Caused to Be Presented to, and Paid by, the United States False Claims for Payment Related to the Purchase of the Drug Cipro® After the CIPRO Market Exclusivity Extension Period, in Violation of 31 U.S.C. § 3729(a)(1)

111. The preceding paragraphs and fact allegations are incorporated herein by reference.

112. During the years following the expiration of the Bayer Cipro® market exclusivity extension, July, 2004 to the present, Defendant Bayer obtained one or more contracts with the United States and presented multiple requests for payment of funds from the United States under such contracts with the United States for the purchase of Cipro® by the United States from Bayer A.G.

113. During the years following the expiration of the Bayer Cipro® market exclusivity extension, July, 2004 to the present, Defendants failed to disclose to the United States prior to Bayer entering new federal contracts for the purchase of Cipro®, and during the performance of these new contracts, that Bayer had obtained the Cipro® market exclusivity extension by fraud and the use of false statements and records, including false medical and scientific data records and reports and false data analyses as described above, and therefore had obtained prior contracts with the United States for the purchase of Cipro® by the use of fraud and false statements.

114. Defendants acted initially, during the negotiation of these new contracts with the United States, and on an on-going basis thereafter during the performance of these contracts, with actual knowledge of the fact that Defendant Bayer had obtained the Cipro® market

exclusivity extension and subsequent contracts with the United States during the market exclusivity extension period via fraud and use of false statements and records, acted in deliberate ignorance of the truth or falsity of these facts, or acted in reckless disregard of the truth of these facts.

115. Defendants failed to disclose to the United States prior to or during the negotiation of these new contracts with the United States, and failed to disclose on an on-going basis thereafter during the performance of these contracts, the material facts that Defendant Bayer had obtained the Cipro® market exclusivity extension and subsequent contracts with the United States during the market exclusivity extension period via fraud and use of false statements and records.

116. During December, 2003 and January – June, 2004, the time of the Bayer Cipro® market exclusivity extension, and the years following the expiration of this extension, July, 2004 to the present, the Bayer Cipro® market exclusivity extension, had Defendants disclosed to the United States the material facts that Defendant Bayer had obtained the Cipro® market exclusivity extension and subsequent contracts with the United States via fraud and use of false statements and records, Defendant Bayer would have been subject to debarment by the United States and would have been ineligible for the contracts it subsequently entered into with the United States for the purchase of CIPRO after the expiration of the CIPRO market exclusivity extension.

117. Had Defendants not failed to disclose these material facts, the United States would have been able to contract with a competitor that produced generic Ciprofloxacin that was not subject to debarment and that was honest and trustworthy and had not engaged in

scientific fraud regarding medical studies, and the United States would not have entered into these new contracts with Bayer A.G. or approved or paid the claims for payment presented by Bayer A.G. to the United States for the continued sale and purchase of Cipro®.

118. During the negotiation of these new contracts with the United States, and on an on-going basis thereafter during the performance of these contracts, Defendants made false representations to the United States, by express and implied statements and certifications and material omissions, that Defendant Bayer was legitimately entitled to enter into new contracts with the United States and not subject to debarment.

119. The United States paid millions of dollars more to Bayer A.G. than it would otherwise have paid to Defendant Bayer via these new contracts for the purchase of Cipro® as a result of these false representations by Defendants to the United States, by express and implied statements and certifications and material omissions, to the effect that Defendant Bayer was legitimately entitled to enter into new contracts with the United States and not subject to debarment.

120. As a result of Defendants' false representations to the United States, by express and implied statements and certifications and material omissions, to the effect that Defendant Bayer was legitimately entitled to enter into new contracts with the United States and not subject to debarment, every contract that Bayer A.G. obtained from the United States and entered into with the United States for the purchase of Cipro® after the expiration of the market exclusivity extension period was a contract obtained under false pretenses and a contract fraudulently obtained.

121. As a result of the foregoing facts, every claim for payment under each of these new federal contracts for the purchase of CIPRO after the expiration of the market exclusivity extension period was a false claim under the False Claims Act, *See*, *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776 (4th Cir.1999), and Defendants' aforementioned false representations and statements, including material omissions, caused each of these false claims to be approved and paid by the United States.

122. Had Defendants timely disclosed the material facts that it had obtained the Cipro® market exclusivity extension by fraud and the use of false statements and records, including false medical and scientific data records and reports and false data analyses as described above, and therefore had obtained prior contracts for the purchase of Cipro® with the United States by the use of fraud and false statements, the United States would not have entered into these new contracts for the purchase of Cipro® and would not have approved or paid the claims for payment presented by Bayer A.G. to the United States under these new contracts for the purchase of Cipro®.

123. The damages to the United States under the FCA from the Defendants' false representations used to obtain these new contracts for the purchase of Cipro® and Defendant Bayer's resulting false claims for payment under these contracts which were approved and paid, would be several million dollars (prior to trebling as required under the False Claims Act).

Count 5:Defendants Knowingly Presented Or Caused to Be Presented to, and Paid by, the United States False Claims for Payment Under Contracts Related to the Purchase of Drugs and Products Other Than CIPRO, in Violation of 31 U.S.C. § 3729(a)(1)

124. The preceding paragraphs and fact allegations are incorporated herein by reference.

125. During the time of the Bayer Cipro® patent market exclusivity extension, December, 2003 and January – June, 2004, and the years following the expiration of the extension, July, 2004 to the present, Defendant Bayer obtained one or more contracts with the United States and presented multiple requests for payment of funds from the United States under such contracts with the United States for the purchase of drugs and products other than Cipro® by the United States from Bayer A.G.

126. During the time of this Bayer Cipro® patent market exclusivity extension, December, 2003 and January – June, 2004, and the years following the expiration of this extension, July, 2004 to the present, Defendants failed to disclose to the United States prior to entering new contracts for the purchase of drugs and products other than Cipro®, and during the performance of these new contracts, that Bayer A.G. had obtained the Cipro® market exclusivity extension by fraud and the use of false statements and records, including false medical and scientific data records and reports and false data analyses as described above, and therefore had obtained prior contracts with the United States by the use of fraud and false statements.

127. Defendants acted initially, during the negotiation of these new contracts with the United States for the purchase of drugs and products other than Cipro®, and on an on-going basis thereafter during the performance of these contracts, with actual knowledge of the fact that Defendant Bayer had obtained the Cipro® market exclusivity extension and subsequent contracts with the United States during and after the market exclusivity extension period via fraud and use of false statements and records, acted in deliberate ignorance of the truth or falsity of these facts, or acted in reckless disregard of the truth of

these facts.

128. Defendants failed to disclose to the United States prior to or during the negotiation of these new contracts with the United States for the purchase of drugs and products other than Cipro®, and failed to disclose on an on-going basis thereafter during the performance of these contracts, the material facts that Defendant Bayer had obtained the Cipro® market exclusivity extension and subsequent contracts with the United States during and after the market exclusivity extension period via fraud and use of false statements and records.

129. During the time of the Bayer Cipro® market exclusivity extension, December, 2003 and January – June, 2004, and the years following the expiration of this extension, July, 2004 to the present, had Defendants disclosed to the United States the material facts that Defendant Bayer had obtained the Cipro® market exclusivity extension and subsequent contracts with the United States via fraud and use of false statements and records, Defendant Bayer would have been subject to debarment by the United States and would have been ineligible for the contracts it subsequently entered into with the United States for the purchase of drugs and products other than Cipro® during and after the expiration of the Cipro® market exclusivity extension.

130. Had Defendants not failed to disclose these material facts, the United States would have been able to contract with a competitor of Bayer that produced these drugs and products other than Cipro® that was not subject to debarment and that was honest and trustworthy and had not engaged in scientific fraud regarding medical studies, and the United States would not have entered into these new contracts with Bayer or approved or paid the

claims for payment presented by Bayer A.G. to the United States for the purchase by the United States of drugs and products other than Cipro®.

131. During the negotiation of these new contracts with the United States for the purchase of drugs and products other than Cipro®, and on an on-going basis thereafter during the performance of these contracts, Defendants made false representations to the United States, by express and implied statements and certifications and material omissions, that Defendant Bayer was legitimately entitled to enter into new contracts with the United States and not subject to debarment.

132. The United States paid millions of dollars more to Bayer A.G. than it would otherwise have paid to Defendant Bayer via these new contracts for the purchase of drugs and products other than Cipro® as a result of these false representations by Defendants to the United States, by express and implied statements and certifications and material omissions, to the effect that Defendant Bayer was legitimately entitled to enter into new contracts with the United States and not subject to debarment.

133. As a result of Defendants' false representations to the United States, by express and implied statements and certifications and material omissions, to the effect that Defendant Bayer was legitimately entitled to enter into new contracts with the United States and not subject to debarment, every contract that Bayer A.G. obtained from the United States and entered into with the United States for the purchase of drugs and products other than Cipro® during and after the expiration of the market exclusivity extension period was a contract obtained under false pretenses and a contract fraudulently obtained.

134. As a result of the foregoing facts, every claim for payment made by Bayer under each of

these new federal contracts for the purchase of drugs and products other than Cipro® during and after the expiration of the Cipro® market exclusivity extension period was a false claim under the False Claims Act, *See*, *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776 (4th Cir.1999), and Defendants' aforementioned false representations and statements, including material omissions, caused each of these false claims to be approved and paid by the United States.

135. Had Defendants timely disclosed the material facts that Bayer had obtained the Cipro® market exclusivity extension by fraud and the use of false statements and records, including false medical and scientific data records and reports and false data analyses as described above, and therefore had obtained prior contracts with the United States by the use of fraud and false statements, the United States would not have entered into these new contracts for the purchase of drugs and products other than Cipro® and would not have approved or paid the claims for payment presented by Bayer A.G. to the United States under these new contracts for the purchase of drugs and products other than Cipro®.

136. The damages to the United States under the FCA from the Defendants' false representations used to obtain these new contracts for the purchase of drugs and products other than Cipro® and Defendant Bayer's resulting false claims for payment under these contracts which were approved and paid, are estimated, based on Bayer's prior instances of overcharging the government, to be several million dollars (prior to trebling as required under the False Claims Act).

V. PRAYER FOR RELIEF

WHEREFORE, Plaintiff United States and Relator Dr. Juan N. Walterspiel respectfully request that this court:

a. Declare the Defendants to have violated the False Claims Act as alleged in each of the above stated counts;

b. Award to the United States and the Qui Tam Relator Dr. Walterspiel the treble damages provided for in the False Claims Act in the amount of three times the total value of damages to the United States resulting from these False Claims Act violations by Defendants , which damages are estimated to be greater than $25,000,000 before trebling, with 70% of this amount to be retained by the federal government and 30% of this amount to be recovered by Qui Tam Relator Dr. Walterspiel pursuant to the provisions of the False Claims Act at 31 U.S.C. § 3730;

c. Assess, pursuant to the applicable penalty provisions of the False Claims Act, the maximum penalties of $10,000 against the Defendant for each false claim and false statement and record presented by them;

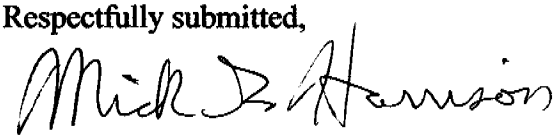
d. Award to Qui Tam Relator Dr. Walterspiel his costs and expenses required to prosecute this action, including reasonable attorney fees, expert witness fees and other expenses and costs as provided for in the False Claims Act, 31 U.S.C. § 3730; and

e. Award the United States and Qui Tam Relator such other and further relief as this Court may deem proper.

Jury Demand

Plaintiff United States and Relator Dr. Walterspiel hereby demand a trial by jury on all claims and issues so triable.

Respectfully submitted,



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